

What is claimed is:

1. A method for producing a decellularized extracellular matrix material containing a biological material, wherein the method comprises:

(a) conditioning body tissue of a donor animal to produce the biological material in an amount different than the amount of the biological material that the body tissue would produce absent the conditioning;

(b) allowing the conditioned body tissue to produce the biological material;

(c) harvesting the conditioned body tissue from the donor animal; and

(d) decellularizing the conditioned body tissue to obtain the extracellular matrix material containing the biological material.

2. The method of claim 1, wherein steps (a) and (b) are conducted before the harvesting in step (c).

3. The method of claim 1, wherein steps (a) and (b) are conducted after the harvesting in step (c).

4. The method of claim 3, wherein step (b) comprises culturing the conditioned body tissue in a bioreactor to allow the conditioned body tissue to produce the biological material.

5. The method of claim 1 further comprising monitoring the amount of biological material produced by the conditioned body tissue.

6. The method of claim 1 further comprising delivering a therapeutic agent to the body tissue before the conditioning in step (a).

7. The method of claim 1 further comprising delivering a therapeutic agent to the body tissue after the conditioning in step (a).

8. The method of claim 1 further comprising adding a therapeutic agent to the decellularized extracellular matrix material.

9. The method of claim 1, wherein the donor animal is a mammal.

10. The method of claim 1, wherein the mammal is selected from the group consisting of cows, pigs, horses, chickens, cats, dogs, rats, monkeys, and humans.

11. The method of claim 1, wherein the body tissue is selected from the group consisting of epithelial tissue, connective tissue, muscle tissue, and nerve tissue.

12. The method of claim 1, wherein the body tissue is selected from the group consisting of lymph vessels, blood vessels, heart valves, myocardium, pericardium, pericardial sac, dura mater, meniscus, omentum, mesentery, conjunctiva, umbilical cords, bone marrow, bone pieces, ligaments, tendon, tooth implants, dermis, skin, muscle, nerves, spinal cord, pancreas, gut, intestines, peritoneum, submucosa, stomach, liver, and bladder.

13. The method of claim 1, wherein the biological material is selected from the group consisting of vascular endothelial growth factor (VEGF), transforming growth factor (TGF), fibroblast growth factor (FGF), epidermal growth factor (EGF), cartilage growth factor (CGF), nerve growth factor (NGF), keratinocyte growth factor (KGF), skeletal growth factor (SGF), osteoblast-derived growth factor (BDGF), hepatocyte growth factor (HGF), insulin-like growth factor (IGF), cytokine growth factors (CGF), platelet-derived growth factor (PDGF), hypoxia inducible factor-1 (HIF-1), stem cell derived factor (SDF), stem cell factor (SCF), endothelial cell growth supplement (ECGS), granulocyte macrophage colony stimulating factor (GM-CSF), growth differentiation factor (GDF), integrin modulating factor (IMF), calmodulin (CaM), thymidine kinase (TK), tumor necrosis factor (TNF), growth hormone (GH), bone morphogenic proteins (BMP), matrix metalloproteinase (MMP), tissue inhibitor of matrix metalloproteinase (TIMP), interferon, interleukins, cytokines, integrin, collagen (all types), elastin, fibrillins, fibronectin, laminin, glycosaminoglycans, vitronectin, proteoglycans, transferrin, cytotactin, cell binding domains (*e.g.*, RGD), tenascin, and lymphokines.

14. The method of claim 1, wherein the body tissue is conditioned by a process selected from the group consisting of biological conditioning, chemical conditioning, pharmaceutical conditioning, physiological conditioning, and mechanical conditioning.

15. The method of claim 14, wherein the biological conditioning comprises transfecting the body tissue with a nucleic acid that encodes the biological material.

16. The method of claim 14, wherein the chemical conditioning comprises incubating the body tissue in a hypotonic or hypertonic solution.

17. The method of claim 14, wherein the pharmaceutical conditioning comprises delivering a therapeutic agent to the body tissue.

5 18. The method of claim 14, wherein the physiological conditioning comprises exposing the body tissue to heat shock or cryopreservation followed by thawing.

19. The method of claim 14, wherein the mechanical conditioning comprises applying a force to the body tissue.

10 20. The method of claim 19, wherein the force is selected from the group consisting of a mechanical force, centrifugal force, electrical force, electromagnetic force, hydrostatic or hydrodynamic force, sound wave, and ultrasound wave.

21. A decellularized extracellular matrix material produced by the method of claim 1 for injection into a subject.

15 22. A decellularized extracellular matrix material produced by the method of claim 1 for implantation into a subject.

23. A tissue regeneration scaffold for implantation into a patient comprising the decellularized extracellular matrix material produced by the method of claim 1.

24. A method of using the decellularized extracellular matrix material produced by the method of claim 1 to repair injured body tissue of a patient.

20 25. A method of using the decellularized extracellular matrix material produced by the method of claim 1 to regenerate injured body tissue of a patient.

26. A method of using the decellularized extracellular matrix material produced by the method of claim 1 to strengthen injured body tissue of a patient.

25 27. A method for producing a decellularized extracellular matrix material containing a biological material, wherein the method comprises:

- (a) conditioning body tissue of a donor animal to produce the biological material in an amount different than the amount of the biological

material that the body tissue would produce absent the conditioning,
wherein the conditioning comprises transfecting the body tissue with a
nucleic acid that encodes the biological material;

- (b) allowing the conditioned body tissue to produce the biological
material;
- (c) harvesting the conditioned body tissue from the donor animal; and
- (d) decellularizing the conditioned body tissue to obtain the extracellular
matrix material containing the biological material.

28. The method of claim 27, wherein steps (a) and (b) are conducted before the
harvesting in step (c).

29. The method of claim 27, wherein steps (a) and (b) are conducted after the
harvesting in step (c).

30. The method of claim 27, wherein the biological material is vascular
endothelial growth factor (VEGF).

31. A method for producing a decellularized extracellular matrix material
containing a biological material, wherein the method comprises:

- (a) conditioning a body tissue of a donor animal to produce the biological
material in an amount different than the amount of the biological
material that the body tissue would produce absent the conditioning,
wherein the conditioning comprises applying a mechanical force to
the body tissue;
- (b) allowing the conditioned body tissue to produce the biological
material;
- (c) harvesting the conditioned body tissue from the donor animal; and
- (d) decellularizing the conditioned body tissue to obtain the extracellular
matrix material containing the biological material.

32. The method of claim 31, wherein steps (a) and (b) are conducted before the
harvesting in step (c).

33. The method of claim 31, wherein steps (a) and (b) are conducted after the
harvesting in step (c).

34. The method of 31, wherein the body tissue is small intestine tissue and the mechanical force is produced by the expansion of a balloon against the small intestine tissue.

35. A method for producing a tissue regeneration scaffold for implantation into a patient comprising:

- 5 (a) conditioning body tissue of a donor animal to produce the biological material in an amount different than the amount of the biological material that the body tissue would produce absent the conditioning;
- (b) allowing the conditioned body tissue to produce the biological material;
- 10 (c) harvesting the conditioned body tissue from the donor animal;
- (d) decellularizing the conditioned body tissue to obtain the extracellular matrix material containing the biological material; and
- (e) forming the tissue regeneration scaffold from the decellularized extracellular matrix material containing the biological material.

15 36. A method for producing a tissue regeneration scaffold for implantation into a patient comprising:

- (a) harvesting body tissue from a donor animal;
- (b) conditioning the harvested body tissue *in vitro* to produce a biological material in an amount different than the amount of the biological material that the body tissue would produce absent the conditioning;
- 20 (c) culturing the harvested and conditioned body tissue in a bioreactor to allow the body tissue to produce the biological material;
- (d) decellularizing the conditioned body tissue to obtain the extracellular matrix material containing the biological material; and
- 25 (e) forming the tissue regeneration scaffold from the decellularized extracellular matrix material containing the biological material.

37. An implantable medical device comprising a surface and a decellularized extracellular matrix material comprising a biological material, wherein the decellularized matrix material is produced by a method comprising:

- 30 (a) conditioning body tissue of a donor animal to produce the biological material in an amount different than the amount of the biological material that the body tissue would produce absent the conditioning;

- (b) allowing the conditioned body tissue to produce the biological material;
- (c) harvesting the body tissue from the donor animal; and
- (d) decellularizing the conditioned body tissue to obtain the extracellular matrix material containing the biological material.

5

38. The device of claim 37, wherein the decellularized extracellular matrix material is disposed upon the surface of the device.

39. The device of claim 37, wherein the device is a stent.

40. The device of claim 37, wherein the device is an artificial heart.

10

41. The device of claim 37, wherein the biological material is elastin.